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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,674	10/09/2001	Hannes Loferer	GPCG-P01-019	5774

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,674	LOFERER ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Vacation of all Previous Actions

1. At the outset, the examiner wishes to set forth that the office actions of June 2, 2004 and October 1, 2004 have been vacated.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1(a), 2, 4-5, 8-9, 14(b) and 15 are drawn to a method for identifying an antagonist or inhibitor of the expression of a single gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC encoding a polypeptide essential for bacterial growth or survival comprising a plurality of said candidate antagonist or inhibitors for the inhibition or reduction of transcription of said gene or a fragment or derivative thereof, classified in class 435, subclass 69.2.

B. Claims 1(b), 2, 4-5, 8-9, 14(c) and 15 are drawn to a method for identifying an antagonist or inhibitor of the expression of a single gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC encoding a polypeptide essential for bacterial growth or survival comprising a plurality of said candidate antagonist or inhibitors for the inhibition or reduction of translation of mRNA transcribed

from said gene or fragment or derivative thereof, classified in class 536 subclass 24.5.

C. Claims 3-5 and 8-9 are drawn to a method for testing a candidate antagonist or inhibitor of the function of a single gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC, classified in class 435, subclass 71.1.

D. Claims 6 and 8-9 are drawn to a method for designing an improved antagonist or inhibitor for the treatment of a bacterial infection or disorder or disease comprising the identification of the binding site of an antagonist or inhibitor of a single polypeptide selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC, classified in class 435, subclass 41.

E. Claims 7-13 are drawn to an antagonist or inhibitor of the activity of a single selected polypeptide encoded by a gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC, classified in class 424, subclass 278.1.

F. Claims 14(a) and 15 are drawn to a method for identifying an antagonist or inhibitor comprising the inhibition or reduction of activity of a single

polypeptide, fragment, derivative or ortholog, classified in class 536, subclass 23.7.

G. Claims 14(a-c) and 15 are drawn to a method for identifying an antagonist or inhibitor of the activity of a single polypeptide encoded by a gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC, fragment, derivative or ortholog comprising the test of 14(a-c), classified in class 435, subclass 70.1.

H. Claim 16 is drawn to a method for treating or preventing bacterial infections, classified in class 424, subclass 184.1.

I. Claims 17 and 22-26 are drawn to a method for screening for a molecule interacting with a single polypeptide encoded by a gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC classified in class 435, subclass 69.7.

J. Claims 19 and 20-21 are drawn to the use of conditional mutants in a single gene selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC, classified in class 424, subclass 282.1.

3. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions A-D and F-J are related as distinct methods because they are different methods with different method steps; reagents; functions and those result in different final outcomes. First, the instant specification does not disclose that these methods would be used together; rather the specification states that the methods are separate and distinct. The methods are all unrelated as they comprise distinct steps and utilize different products that demonstrate that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for the method of Group A drawn to the inhibition or reduction of transcription of said gene differs significantly from the other methods. For instance, the method of Group H is necessary to treat or prevent bacterial infections and such steps are not be necessary to practice the other methods. In this case, Group B is separate and distinct, from Groups A, C-d, and any of F-J, since only group B comprises a plurality of said candidate antagonist or inhibitors for the inhibition or reduction of translation of mRNA transcribed from said gene. Therefore, each method is divergent with respect to the amounts of reagents used and their associated steps. For these reasons the inventions A-D and F-J are patentably distinct.

Furthermore, searching the inventions of groups A-D and F-J would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method for identifying an antagonist or inhibitor of the expression of a single gene encoding a polypeptide essential for bacterial growth or survival comprising a plurality of said candidate antagonist or inhibitors for the inhibition

or reduction of translation of mRNA transcribed from said gene require a different search, than the other methods. Thus, a search drawn to said method is not necessary for a determination of novelty and unobviousness of the method of group D which is drawn to a method for designing an improved antagonist or inhibitor for the treatment of a bacterial infection or disorder or disease. Furthermore, the method D may be known even if the method of group F is novel. In addition, the technical literature search for a method for screening for a molecule interacting with a single polypeptide encoded by a gene (group I) and the method for testing a candidate antagonist or inhibitor of the function of a single gene (group C) are not coextensive, since the method of group I may be characterized in the technical literature prior to discovery of the method of group C.

(ii) Inventions A-J are unrelated with respect to the polypeptide or gene being selected from the group consisting of ygbB, yfhC, yacE, ychB, yejD, yrfI, yggJ, yjeE, yiaO, yrdC, yhbC, ygbP, ybeY, gcpE, kdtB, pfs, ycaJ, b1808, yeaA, yagF, b1983, yidD, yceG and yjbC are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The groups are drawn to a plurality of disclosed patentably distinct polypeptides and genes comprising materially different amino acid sequences as evidence by separate SEQ ID Numbers provided within Figure 1. The separate polypeptides and genes bear distinct structural or biochemical properties. Therefore, each disclosed

patentably distinct gene or polypeptide is considered a separate invention. The instant specification does not disclose that these genes or polypeptides within each method would be used together. The methods as defined by groups A-J are unrelated as they can utilize different polypeptides and genes, which demonstrates that each method has a different function and mode of operation. Each invention performs its function using a structurally and functionally divergent material. Moreover, the sequences represented by the different polypeptides and genes are necessary within the methods and differ significantly for each of the methods. The sequences within the methods constitute patentably distinct inventions. For instance, the groups are directed to distinct physically, structurally, and functionally polypeptides or genes and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each gene comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Therefore, each method is unrelated. For these reasons the Inventions A-O are patentably distinct.

Thus when applicant elects a group, applicant must also elect a single gene or polypeptide.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions

unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

Furthermore, the distinct polypeptides and genes require separate and distinct searches. In the instant case, the search of the methods and sequences are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also found within the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to a particular sequence which would not have described the other sequences. Searching, therefore is not coextensive. In addition, the claims include amino acid sequences whose search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups A-J together.

4. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups A-J have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups A-J together.

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search

required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 27, 2006